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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,486	11/13/2003	David A. Schechter	2876	8330

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UNITED STATES SURGICAL,
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EXAMINER

TOY, ALEX B

ART UNIT PAPER NUMBER

3739

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/712,486

Applicant(s)

SCHECHTER ET AL.

Examiner

Alex B. Toy

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 9-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's Request for Continued Examination filed on November 13, 2006. All previous prior art rejections are withdrawn, but new grounds of rejection are made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the original specification as filed, applicant provided proper written description for the offset distance X being about 0.005 inches to about 0.200 inches. Applicant, however, did not provide a proper written description for the more specific range of 0.005 inches to less than 0.04 inches. This is analogous to originally disclosing and claiming only a material comprising a metal and then amending the claim to recite a material comprising specifically titanium.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-8, and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phan (U.S. Pat No. 6,932,816 B2) in view of Hooven (U.S. Pat. No. 6,086,586).

Regarding claim 1, Phan discloses a tissue or vessel sealing instrument, comprising:

a housing 242 having a shaft (internal and not shown) attached thereto (col. 2, ln. 46-65 and Fig. 34); and

an end effector 22, 24 assembly attached to a distal end of the shaft, the end effector assembly including first 22 and second 24 jaw members attached thereto made from a substantially rigid material (col. 5, ln. 61 – col. 6, ln. 2, col. 17, ln. 16-17, and Fig. 5), the jaw members being movable relative to one another from a first position for

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approximating tissue to at least one additional position for grasping tissue therebetween (Figs. 4-5);

each of the jaw members including an elastomeric material 106 disposed on an inner facing tissue contacting surface thereof (col. 6, ln. 32-35 and Figs. 4-8), each of the elastomeric materials including an electrode 108 disposed therein, the elastomeric material being adapted to compress or deflect about 0.001 inches to about 0.015 inches when the force used to close the jaw members is between about 40 psi to about 230 psi; and

wherein the substantially rigid material of the jaw members resists deformation when the force used to close the jaw members is between about 40 psi to about 230 psi.

Since the elastomeric and rigid materials of Phan are identical to applicant's disclosed materials, they are deemed to inherently, or at least obviously, possess the same material properties at the claimed compression force range.

The claim differs from Phan in calling for the electrodes to be offset a distance X relative to one another such that when the jaw members are closed about the tissue and when the electrodes are activated, electrosurgical energy flows through the tissue in a generally coplanar manner relative to the tissue contacting surfaces. Hooven, however, discloses jaw members with electrodes 42, 44, 46, 48 arranged as claimed so that the flow of current between the electrodes naturally stops when coagulation is complete to prevent thermal damage due to over-coagulation outside the jaws (col. 1, ln. 29 – col. 2, ln. 8, col. 4, ln. 30-45, and Figs. 5-6 and 9). Therefore, it would have

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been obvious to one of ordinary skill in the art at the time the invention was made to have arranged electrodes on the device of Phan as claimed in view of the teaching of Hooven so that the flow of current between the electrodes naturally stops when coagulation is complete to prevent thermal damage due to over-coagulation outside the jaws.

Regarding claim 2, Phan further discloses that the elastomeric material 106 is silicone and/or polyurethane (col. 6, ln. 32-35 and Figs. 4-8).

Regarding claim 3, Hooven further discloses that the offset distance X is in the range of about 0.005 inches (0.127 mm) to about 0.200 inches (5.08 mm) (col. 4, ln. 63-65 and Fig. 9).

Regarding claims 4 and 5, Phan further discloses at least one temperature sensor 146 which provides information to a feedback circuit for regulating the electrosurgical energy through the tissue (col. 10, ln. 54 – col. 11, ln. 20 and Figs. 7a).

Regarding claim 7, Phan further discloses that at least one of the jaw members includes at least one electrode 108 across the width thereof and the electrosurgical instrument includes means for selecting one of the electrodes for electrically opposing the electrode disposed on the other of the jaw members, wherein the means includes a sensor which measures at least one of tissue impedance, tissue temperature, and tissue thickness (col. 11, ln. 21-49 and Figs. 13 and 16a-b)

Regarding claim 8, since the elastomeric materials of Phan are identical to applicant's disclosed materials, they are deemed to inherently, or at least obviously, possess the same claimed comparative tracking index value.

Regarding claim 21, see the preceding rejections of claims 1 and 2.

Regarding claim 22, see the preceding rejections of claims 1 and 3. The claim differs from Phan in view of Hooven in calling for the offset distance X to be in the range of about 0.005 inches to less than 0.04 inches. Applicant, however, has not provided any criticality or unexpected result derived from using this specific range that defines over the 1 mm to 6 mm range taught by Hooven (col. 5, ln. 2-3). Furthermore, since the ranges are so close, it would have been obvious and required only routine skill in the art to use a distance slightly less than 1 mm (0.04 inches) in the device of Hooven.

Regarding claim 23, see the preceding rejection of claim 1. The claim differs from Phan in view of Hooven in calling for the distance X to be variable depending on the thickness of the tissue between the jaw members. Hooven teaches varying the offset distance X between 1 mm and 6 mm but does not specifically disclose varying the distance based on the thickness of the tissue between the jaw members. It would have been obvious and intuitive to one of ordinary skill in the art, however, that tissue thickness affects the separation distance of the electrodes that is required for effective treatment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the distance X of Phan in view of Hooven variable depending on the thickness of the tissue between the jaw members.

Response to Arguments

Applicant's arguments with respect to the pending claims have been fully considered and are persuasive. Therefore, the previous rejections have been withdrawn. However, upon further consideration, new grounds of rejection are made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT *AT*
12/4/06

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER